

The Honorable Barbara J. Rothstein

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF WASHINGTON  
AT SEATTLE

KENNETH MILTON, *et al.*,

Plaintiffs,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

NO. 23-cv-1251

**ORDER GRANTING IN PART AND  
DENYING IN PART MOTION TO  
DISMISS**

**I. INTRODUCTION**

On July 18, 2023, Plaintiffs, Kenneth and Josephine Milton, brought this product liability suit against American Medical Systems, Inc. and Boston Scientific Corporation for injuries arising from a purported defect in a medical device implanted during Mr. Milton's October 2019 surgery. Boston Scientific<sup>1</sup> removed the case from Snohomish County Superior Court to this Court on August 16, 2023. Currently pending before the Court is Boston Scientific's Motion to Dismiss, ECF No. 7, which Plaintiffs have opposed. Having reviewed the parties' filings<sup>2</sup> and the relevant legal

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<sup>1</sup> Boston Scientific acquired American Medical Systems, Inc. "men's urology portfolio" in August 2015. Not. Removal ¶¶ 6, 13, n.1, ECF No. 1; Mot. 1 n.1, ECF No. 7. The women's health portfolio is now ASTORA Women's Health, and American Medical Systems, Inc. no longer exists. *Id.*

<sup>2</sup> Motion, ECF No. 7; Response in opposition, ECF No. 8; and Reply, ECF No. 10.

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authorities, the Court will grant in part and deny in part Boston Scientific’s dismissal motion with leave to amend. The reasoning for the Court’s decision follows.

## II. BACKGROUND<sup>3</sup>

On October 19, 2019, Mr. Milton had a medical device surgically implanted to resolve issues with urinary incontinence following extensive radiation for prostate cancer. Compl. ¶¶ 9-10, ECF No. 1-1. The device, Boston Scientific’s AMS 800 Artificial Urinary Sphincter (“AMS 800”), provided manual emptying of the bladder. *Id.* ¶ 9, Mot. 1. “The device failed and leaked urine from the beginning.” Compl. ¶ 10. Plaintiffs allege that the cause of the leakage was unclear, and after nine months, Mr. Milton’s doctor suspected that the device was faulty. *Id.* A second surgery was scheduled to remove and replace the device. *Id.*

On August 6, 2020, Mr. Milton underwent a second surgery and after activation of the replacement device, the leakage ceased. *Id.* ¶¶ 10-11. A device representative was present, and upon inspection of the removed device, acknowledged that it was faulty and had caused the leakage. *Id.* ¶ 11. The Miltons allege physical and emotional damages for the period from October 19, 2019 through August 6, 2020 due to the continued leakage caused by the faulty device. *Id.* ¶¶ 12, 21-22.

The Miltons filed suit in the Snohomish County Superior Court on July 18, 2023, asserting two causes of action: (1) strict liability and negligence in violation of the Washington Products Liability Act (“WPLA”), RCW 7.72, *et seq.*, citing design and manufacturing defects; and warranty claims (2) a breach of warranty claim under RCW 62A (Uniform Commercial Code). *Id.* ¶¶ 13-17; ¶¶ 18-20. The case was removed to this Court on August 16, 2023. Not. Removal, ECF No. 1.

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<sup>3</sup> Facts are taken from the Complaint, ECF No. 1-1, and are assumed to be true for purposes of ruling on the motion to dismiss. *See Erickson v. Pardus*, 551 U.S. 89, 94 (2007).

1 Boston Scientific filed the pending motion on August 28, 2023, contending that the lawsuit  
2 is subject to dismissal on three grounds: (1) it is untimely under the governing three-year statute of  
3 limitations; (2) the claims are preempted because the lawsuit concerns a Class III medical device;  
4 and (3) the conclusory allegations fail to state a plausible claim. Mot. 2.

### 5 **III. LEGAL STANDARD**

6 A motion to dismiss for failure to state a claim under Rule 12(b)(6) is properly granted if  
7 the complaint does not “contain sufficient factual matter, accepted as true, to ‘state a claim to relief  
8 that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp.*  
9 *v. Twombly*, 550 U.S. 544, 570 (2007)). The plaintiff must plead “factual content that allows the  
10 court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.*  
11 “A complaint may fail to show a right to relief either by lacking a cognizable legal theory or by  
12 lacking sufficient facts alleged under a cognizable legal theory.” *Woods v. U.S. Bank N.A.*, 831  
13 F.3d 1159, 1162 (9th Cir. 2016). When considering a motion to dismiss under Rule 12(b)(6), courts  
14 must accept the factual allegations in the complaint as true and construe such allegations in the  
15 light most favorable to the plaintiff. *Interpipe Contracting, Inc. v. Becerra*, 898 F.3d 879, 886-87  
16 (9th Cir. 2018).

### 17 **IV. DISCUSSION**

#### 18 **A. Timeliness**

19 Boston Scientific contends that Plaintiffs case is barred by the statute of limitations.  
20 Because timeliness is a threshold inquiry, the Court will address it first. Generally, a motion to  
21 dismiss filed under Rule 12(b)(6) does not reach the merits of affirmative defenses, but if all facts  
22 necessary to the affirmative defense are clearly alleged on the face of the complaint, the defense  
23 may be raised by a motion to dismiss. *Seven Arts Filmed Ent. Ltd. v. Content Media Corp. PLC*,

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1 733 F.3d 1251, 1254 (9th Cir. 2013) (quoting *Conerly v. Westinghouse Elec. Corp.*, 623 F.2d 117,  
2 119 (9th Cir. 1980)).

3 The statute of limitations for a product liability claim under the WPLA is “three years from  
4 the time the claimant discovered or in the exercise of due diligence should have discovered the  
5 harm and its cause.” RCW 7.72.060(3). Each party offers a different date for when it would have  
6 been reasonable for the Plaintiffs, exercising due diligence, to discover the harm and its cause.

7 Boston Scientific argues that Plaintiffs should have been aware of their possible claims by  
8 October 2019, after Mr. Milton had the device implanted and immediately experienced  
9 complications that were directly linked to the surgery and the urinary implant device. Mot. 4-5.  
10 Boston Scientific asserts that Plaintiffs’ lawsuit, filed on July 18, 2023, is more than three years  
11 later, and is time-barred. *Id.* Plaintiffs respond that they did not discover that the device was faulty,  
12 causing the leakage, until the second surgery on August 6, 2020. Opp’n 2, ECF No. 8. They assert  
13 that the lawsuit was, therefore, timely filed within the three-year limitation period. *Id.*

14 When a party should have discovered a cause of action is ordinarily a question of fact. *Green*  
15 *v. A.P.C. (Am. Pharm. Co.)*, 136 Wn.2d 87, 100 (1998). As the defendant raising the statute of  
16 limitations as an affirmative defense, Boston Scientific has the burden of proving the action is time  
17 barred. *Cal. Sansome Co. v. U.S. Gypsum*, 55 F.3d 1402, 1406 (9th Cir. 1995). Plaintiffs’  
18 allegations include that the cause of the leakage “from the beginning” was unclear, that after nine  
19 months, Mr. Milton’s doctor “suspected the device itself was faulty and causing the continued  
20 leakage,” and that it was only on inspection of the device after its removal on the surgery on August  
21 6, 2020, it was determined to be faulty. Compl. ¶¶ 10-11. The Court is not persuaded that the only  
22 reasonable inference to be drawn from the Plaintiffs’ allegations is that they were on notice by  
23 October 2019. Boston Scientific has not met its burden of showing that the lawsuit is untimely.

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## B. Plaintiffs' Claims

### 1. Design Defect

Boston Scientific argues that Plaintiffs have failed to plausibly allege a design defect. Mot. 12-13.<sup>4</sup> Plaintiffs concede that their “claims regarding design defect and effectiveness are preempted.” Opp’n 3. As such, further discussion of the design defect claim is unnecessary.

### 2. Negligence

Boston Scientific argues that Plaintiffs’ common-law negligence claim is preempted by the WPLA and must be dismissed. Mot. 11-12, 15; Reply 4, ECF No. 10. The WPLA “created a single cause of action for product-related harms and supplants previously existing common law remedies, including common law actions for negligence.” *Wash. State Physicians Ins. Exch. & Ass’n v. Fisons Corp.*, 858 P.2d 1054, 1067 (Wash. 1993); *see also Macias v. Saberhagen Holdings, Inc.*, 282 P.3d 1069, 1073-74 (Wash. 2012) (“Insofar as a negligence claim is product-based, the negligence theory is subsumed under the WPLA product liability claim.”). Under the WPLA, “[a] product manufacturer is subject to liability to a claimant if the claimant’s harm was proximately caused by the negligence of the manufacturer in that the product was not reasonably safe as designed or not reasonably safe because adequate warnings or instructions were not provided.” RCW 7.72.030(1).

Although it is not clear, Plaintiffs appear to assert negligence as a part of their WPLA cause of action rather than as a separate common-law claim. *See* Compl. ¶ 13. However, to the extent

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<sup>4</sup> Boston Scientific also contends that Plaintiffs’ claims are preempted by the Medical Device Amendments (“MDA”), 21 U.S.C. §§ 360c *et seq.*, to the Federal Food, Drug and Cosmetics Act (“FDCA”), 21 U.S.C. §§ 301 *et seq.*, because the AMS 800 is a Class III medical device. Mot. 5-12. As previously noted, a motion to dismiss filed under Rule 12(b)(6) does not typically reach the merits of an affirmative defense. It is not clear from the face of the complaint that Plaintiffs either have not or cannot plead plausible parallel claims, and, therefore, the Court does not address the federal preemption argument at this time.

that Plaintiffs intended to assert a separate cause of action for negligence, it is dismissed because the WPLA is the exclusive remedy.

### 3. Manufacturing Defect

Boston Scientific argues that Plaintiffs' claims are implausible because they fail to allege any defect and "merely allege the product was defectively manufactured, and contains no supporting allegations." Mot. 12-14.

First, Plaintiffs may bring a single WPLA claim under any or all of four theories: (1) a defective design; (2) a failure to warn; (3) a defective manufacture; or (4) a breach of express or implied warranty. *Staub v. Zimmer, Inc.*, No. C17-0508JLR, 2017 WL 2506166, at \*2 (W.D. Wash. June 9, 2017) (citing RCW 7.72.030, 16A David K. DeWolf & Keller W. Allen, *Wash. Prac., Tort L. & Prac.* § 17:8 (4th ed. 2013)). A plaintiff is not required to commit at the outset to a specific theory of liability before conducting discovery. *Braden v. Tornier, Inc.*, No. C09-5529RJB, 2009 WL 3188075, at \*3 (W.D. Wash. Sept. 30, 2009). "Requiring plaintiffs to plead facts in support of a specific theory under the WPLA would 'shut the courthouse doors before plaintiffs had an opportunity to meaningfully engage in the process.'" *Frisvold v. Pentair Filtration Sols. LLC*, C17-136RSL, 2017 WL 3236972, at \*2 (W.D. Wash. July 31, 2017) (quoting *Braden*, 2009 WL 3188075, at \*3). However, to survive a motion to dismiss, "the complaint must contain sufficient non-conclusory factual allegations to support at least one avenue of relief." *Staub*, 2017 WL 2506166, at \*2 (citation omitted).

"Simply alleging that Defendants manufacture the product that failed . . . does not create a plausible claim." *Force v. Wright. Med. Tech., Inc.*, 2012 WL 4897165, at \*2 (W.D. Wash. Oct. 15, 2012). Plaintiffs must allege facts showing that "the product deviated in some material way from

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1 the design specifications or performance standards of the manufacturer, or deviated in some  
2 material way from otherwise identical units of the same product line.” RCW § 7.72.030(2)(a).

3 Here, Plaintiffs allege that the device was intended “to provide manual emptying of the  
4 bladder” to resolve “urinary incontinence,” and the original device implanted “failed and leaked  
5 urine from the beginning.” Compl. ¶¶ 9-10. They further allege that Mr. Milton’s doctor “suspected  
6 the device itself was faulty and causing the continued leakage,” replaced the device, and “[a]fter  
7 activation of the second device, the leakage ceased.” *Id.* ¶¶ 10-11. Plaintiffs also allege that “[a]  
8 representative of the device was present at the second surgery . . . and upon inspecting the original  
9 device, acknowledged the original device which was removed was faulty, causing the leakage.” *Id.*  
10 ¶ 11. Finally, Plaintiffs allege that they suffered specific harms as a result of the original device’s  
11 failure “due to the continued leakage.” *Id.* ¶¶ 12, 17. These allegations show that the original device  
12 deviated in a material way from its expected performance and from an otherwise identical unit. The  
13 Court finds these allegations are sufficient to state a claim for a manufacturing defect under the  
14 WPLA. As such, Plaintiffs’ first cause of action—strict liability and negligence under the WPLA—  
15 survives dismissal and further analysis is unnecessary.

#### 16 **4. Breach of Warranty**

17 Plaintiffs assert a second cause of action—a breach of warranty claim under RCW 62A.  
18 Here, the Court agrees with Boston Scientific that Plaintiffs have failed to state a plausible claim.  
19 Indeed, Plaintiffs did not identify any warranty nor how a warranty was breached. Plaintiffs’ second  
20 cause of action will be dismissed.

#### 21 **C. Leave to Amend**

22 Boston Scientific asks the Court to dismiss Plaintiffs’ claims with prejudice. Reply 6.  
23 However, on a Rule 12(b)(6) motion, “a district court should grant leave to amend even if no request  
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to amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts.” *Cook, Perkiss & Liehe v. N. Cal. Collection Serv.*, 911 F.2d 242, 247 (9th Cir. 1990). Ordinarily, leave to amend a complaint should be freely given. Fed. R. Civ. P. 15(a)(2); *see also Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1051 (9th Cir. 2003) (“[L]eave shall be freely given when justice so requires”). This policy is to be applied with “extreme liberality.” *Owens v. Kaiser Found. Health Plan, Inc.*, 244 F.3d 708, 712 (9th Cir. 2001).

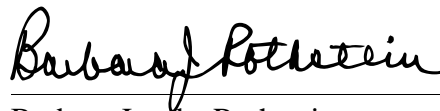
Therefore, if Plaintiffs wish to amend their Complaint, they are permitted to do so within 21 days of the date of this Order.<sup>5</sup>

## V. CONCLUSION

For the foregoing reasons:

1. Boston Scientific’s motion to dismiss is GRANTED IN PART and DENIED IN PART;
  - a. The motion is denied as it pertains to timeliness and Plaintiffs’ first cause of action for a manufacturing defect under the WPLA;
  - b. The motion is granted as it pertains to a design defect, common-law negligence, and Plaintiffs’ second cause of action for breach of warranty;
2. Plaintiffs may file an amended complaint within 21 days of the date of this Order.

DATED this 26th day of October 2023.



Barbara Jacobs Rothstein  
U.S. District Court Judge

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<sup>5</sup> The Court’s Initial Scheduling Order, ECF No. 9, is hereby extended by 30 days. Regardless whether Plaintiffs choose to amend, the case shall proceed pursuant to that Order.

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